

But claims already allowed for preventing. 101
112, 1st preventing - scope of enablement.

652799

8/29/02

Claims

1. A method for treating a subject having an infection of *Clostridium difficile* or preventing an infection of *Clostridium difficile* in said subject, said method comprising administering to said subject an effective amount of rifalazil.

2. The method of claim 1, wherein said rifalazil is administered in an amount between 0.01 and 1000 mg/day.

3. The method of claim 2, wherein said rifalazil is administered in an amount between 1 and 100 mg/day.

4. The method of claim 3, wherein said rifalazil is administered in an amount between 1 and 50 mg/day.

5. The method of claim 4, wherein said rifalazil is administered in an amount between 5 and 25 mg/day.

6. The method of claim 1, wherein said rifalazil is administered for one to fourteen days.

7. The method of claim 6, wherein said rifalazil is administered for three to seven days.

8. The method of claim 1, wherein said rifalazil is administered as a single dose.

9. The method of claim 1, wherein said rifalazil is administered at an initial dose of between 5 and 100 mg, followed by subsequent doses of between 1 and 50 mg for three to seven days.

Rifamycin
known to
treat
C. Diff.

R. Falazil
is a
rifamycin

103 -
obvious.

10. The method of claim 1, wherein said infection of *Clostridium difficile* comprises a strain of *Clostridium difficile* that is resistant to one or more antibiotics selected from the group consisting of vancomycin, rifampicin, rifabutin, rifapentine, rifaximin, and metronidazole.

Both known to treat C. Diff.

11. The method of claim 1, wherein said rifalazil is administered orally, intravenously, subcutaneously, or rectally.

12. The method of claim 1, further comprising administering to said subject an agent that binds *Clostridium difficile* toxin A or toxin B.

13. The method of claim 1, further comprising administering to said subject one or more antibiotics selected from the group consisting of β -lactams, β -lactamase inhibitors, aminoglycosides, tetracyclines, lipopeptides, macrolides, ketolides, lincosamides, streptogramins, sulphonamides, oxazolidinones, quinolones, rifamycins, glycopeptides, metronidazole, garenoxacin, ramoplanin, faropenem, polymyxin, tigecycline, AZD2563, and trimethoprim.

14. The method of claim 13, wherein said β -lactam is selected from the group consisting of penicillins, cephalosporins, carbapenams, and monobactams.

15. The method of claim 14, wherein said penicillin is selected from the group consisting of penicillin G, penicillin V, methicillin, oxacillin, cloxacillin, dicloxacillin, nafcillin, ampicillin, amoxicillin, carbenicillin, ticarcillin, mezlocillin, piperacillin, azlocillin, and temocillin.

penicillin

16. The method of claim 14, wherein said cephalosporin is selected from the group consisting of cephalothin, cephapirin, cephadrine, cephaloridine,

cefazolin, cefamandole, cefuroxime, cephalexin, cefprozil, cefaclor, loracarbef, cefoxitin, cefmatozole, cefotaxime, ceftizoxime, ceftriaxone, cefoperazone, ceftazidime, cefixime, cefpodoxime, cefributen, cefdinir, cefpirome, cefepime, BAL5788, and BAL9141.

17. The method of claim 14, wherein said carbapenam is selected from the group consisting of imipenem, ertapenem, and meropenem.

18. The method of claim 14, wherein said monobactam is astreonam. ✓

19. The method of claim 13, wherein said β -lactamase inhibitor is selected from the group consisting of clavulanate, sulbactam, and tazobactam. ✓

20. The method of claim 13, wherein said aminoglycoside is selected from the group consisting of streptomycin, neomycin, kanamycin, paromycin, gentamicin, tobramycin, amikacin, netilmicin, spectinomycin, sisomicin, dibekalin, and isepamicin.

21. The method of claim 20, wherein said aminoglycoside is gentamicin.

22. The method of claim 13, wherein said tetracycline is selected from the group consisting of tetracycline, chlortetracycline, demeclacycline, minocycline, oxytetracycline, methacycline, and doxycycline.

23. The method of claim 13, wherein said lipopeptide is daptomycin. ✓

24. The method of claim 13, wherein said macrolide is selected from the group consisting of erythromycin, azithromycin, and clarithromycin.

25. The method of claim 24, wherein said macrolide is azithromycin.

26. The method of claim 13, wherein said ketolide is selected from the group consisting of telithromycin and ABT-773. ✓

27. The method of claim 13, wherein said lincosamide is selected from the group consisting of lincomycin and clindamycin.

28. The method of claim 13, wherein said streptogramin is selected from the group consisting of quinupristin and dalfopristin. ✓

29. The method of claim 13, wherein said sulphonamide is selected from the group consisting of sulphanilamide, para-aminobenzoic acid, sulfadiazine, sulfisoxazole, sulfamethoxazole, and sulfathalidine. ✓

30. The method of claim 13, wherein said oxazolidinone is linezolid. ✓

31. The method of claim 13, wherein said quinolone is selected from the group consisting of nalidixic acid, oxolinic acid, norfloxacin, perfloxacin, enoxacin, ofloxacin, ciprofloxacin, temafloxacin, lomefloxacin, fleroxacin, grepafloxacin, sparfloxacin, trovafloxacin, clinafloxacin, gatifloxacin, moxifloxacin, gemifloxacin, and sitafloxacin.

32. The method of claim 31, wherein said quinolone is ciprofloxacin.

33. The method of claim 13, wherein said rifamycin is selected from the group consisting of rifampicin, rifabutin, rifapentine, and rifaximin. ✓

34. The method of claim 13, wherein said antibiotic is metronidazole. ✓

35. The method of claim 13, wherein said glycopeptide is selected from the group consisting of vancomycin, oritavancin, dalbavancin, and teicoplanin.

36. The method of claim 35, wherein said glycopeptide is teicoplanin. ✓

37. The method of claim 35, wherein said glycopeptide is vancomycin.

38. The method of claim 37, wherein said rifalazil and vancomycin are administered simultaneously.

39. The method of claim 37, wherein said rifalazil and vancomycin are administered sequentially.

40. The method of claim 37, wherein said rifalazil and vancomycin are administered within fourteen days of each other.

§ 103
3 mfs.

41. The method of claim 40, wherein said rifalazil and vancomycin are administered within five days of each other.

42. The method of claim 41, wherein said rifalazil and vancomycin are administered within three days of each other.

43. The method of claim 42, wherein said rifalazil and vancomycin are administered within twenty-four hours of each other.

44. The method of claim 37, wherein at least one of said rifalazil and said vancomycin is administered orally.

45. The method of claim 37, wherein both of said rifalazil and said vancomycin are administered orally.

46. The method of claim 37, wherein said vancomycin is administered in an amount between 125 and 2000 mg per day.

47. The method of claim 46, wherein said vancomycin is administered in an amount between 500 and 2000 mg per day.

48. A method of treating a subject having an infection of *Clostridium difficile* or preventing an infection of *Clostridium difficile* in said subject, said method comprising administering to said subject a composition comprising rifalazil and vancomycin.

2 drugs now

49. The method of claim 48, wherein said composition is suitable for oral administration.

50. The method of claim 48, wherein said composition is suitable for intravenous administration.

51. The method of claim 48, wherein said rifalazil is in a unit dosage amount between 0.01 and 100 mg, and said vancomycin is in a unit dosage amount between 125 and 2000 mg.

52. The method of claim 51, wherein said rifalazil is in a unit dosage amount between 1 and 50 mg, and said vancomycin is in a unit dosage amount between 500 and 2000 mg.

Method

53. The method of claim 52, wherein said rifalazil is in a unit dosage amount between 1 and 25 mg, and said vancomycin is in a unit dosage amount between 500 and 2000 mg.

*Article /
Product*

54. A pharmaceutical pack comprising (i) rifalazil in an amount effective to treat a subject having an infection of *Clostridium difficile* or prevent an infection of *Clostridium difficile* in said subject; and (ii) instructions for administering said rifalazil to said subject for treating or preventing a *Clostridium difficile* infection. *K.f?*

55. The pharmaceutical pack of claim 54, wherein said rifalazil is in a unit dosage amount between 0.01 and 100 mg.

56. The pharmaceutical pack of claim 55, wherein said rifalazil is in an amount between 1 and 50 mg.

57. The pharmaceutical pack of claim 56, wherein said rifalazil is in an amount between 1 and 25 mg.

58. The pharmaceutical pack of claim 57, wherein said rifalazil is in an amount between 5 and 25 mg.

59. The pharmaceutical pack of claim 54, further comprising one or more antibiotics selected from the group consisting of β -lactams, β -lactamase inhibitors, aminoglycosides, tetracyclines, lipopeptides, macrolides, ketolides, lincosamides, streptogramins, sulphonamides, oxazolidinones, quinolones, rifamycins, glycopeptides, metronidazole, garenoxacin, ramoplanin, faropenem, polymyxin, tigecycline, AZD2563, and trimethoprim. *+ Antibiotic*

60. The pharmaceutical pack of claim 59, wherein said β -lactam is selected from the group consisting of penicillins, cephalosporins, carbapenams, and monobactams.

61. The pharmaceutical pack of claim 59, wherein said aminoglycoside is selected from the group consisting of streptomycin, neomycin, kanamycin, paromycin, gentamicin, tobramycin, amikacin, netilmicin, spectinomycin, sisomicin, dibekalin, and isepamicin.

62. The pharmaceutical pack of claim 61, wherein said aminoglycoside is gentamicin.

63. The pharmaceutical pack of claim 59, wherein said lipopeptide is daptomycin.

64. The pharmaceutical pack of claim 59, wherein said macrolide is selected from the group consisting of erythromycin, azithromycin, and clarithromycin.

65. The pharmaceutical pack of claim 64, wherein said macrolide is azithromycin.

66. The pharmaceutical pack of claim 59, wherein said streptogramin is selected from the group consisting of quinupristin and dalfopristin.

67. The pharmaceutical pack of claim 59, wherein said oxazolidinone is linezolid.

68. The pharmaceutical pack of claim 59, wherein said quinolone is selected from the group consisting of nalidixic acid, oxolinic acid, norfloxacin, perfloxacin, enoxacin, ofloxacin, ciprofloxacin, temafloxacin, lomefloxacin, fleroxacin, grepafloxacin, sparfloxacin, trovafloxacin, clinafloxacin, gatifloxacin, moxifloxacin, gemifloxacin, and sitafloxacin.

69. The pharmaceutical pack of claim 68, wherein said quinolone is ciprofloxacin.

70. The pharmaceutical pack of claim 59, wherein said rifamycin is selected from the group consisting of rifampicin, rifabutin, rifapentine, and rifaximin.

71. The pharmaceutical pack of claim 59, wherein said glycopeptide is selected from the group consisting of vancomycin, oritavancin, dalbavancin, and teicoplanin.

72. The pharmaceutical pack of claim 71, wherein said glycopeptide is teicoplanin.

73. The pharmaceutical pack of claim 71, wherein said glycopeptide is vancomycin.

74. The pharmaceutical pack of claim 73, wherein said vancomycin is in an amount between 125 and 2000 mg.

75. The pharmaceutical pack of claim 73, wherein said vancomycin is in an amount between 500 and 2000 mg.